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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
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BRUCE GRA	NT		EXAMINER	
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SUITE 500 SAN DIEGO.	CA 92130-2332		ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary

Application No. 08/821,025

Applicant(s)

Bijl et al.

Examiner

Irene Marx

Art Unit 1651



The MAILING DATE of this comm	nunication appears on the cover	sheet with	the correspondence address
communication. - Failure to reply within the set or extended per - Any reply received by the Office later than the earned patent term adjustment. See 37 C	NICATION. The provisions of 37 CFR 1.136 (a). If ate of this communication, than thirty (30) days, a reply within maximum statutory period will apply a riod for reply will, by statute, cause three months after the mailing date of	n no event, the statutor y and will ex the applica	however, may a reply be timely filed
Status 1) Responsive to communication(s)	filed on <i>Feb 12, 2002</i>		·
2a) 💢 This action is FINAL .	2b)☐ This action is non-fin	al.	
3) Since this application is in conditional closed in accordance with the practice.	•		rs, prosecution as to the merits is 11; 453 O.G. 213.
Disposition of Claims			
4) X Claim(s) 1-29, 31, 33-36, and 41	1-67		is/are pending in the application.
4a) Of the above, claim(s) 1-26 an	d 34-36		is/are withdrawn from consideration.
5) Claim(s)		T.	is/are allowed.
6) X Claim(s) 27-29, 31, 33, and 41-6			
7)			is/are objected to.
			to restriction and/or election requirement.
Application Papers 9) The specification is objected to be 10) The drawing(s) filed on	is/are objected to		
Priority under 35 U.S.C. § 119			
13) \square Acknowledgement is made of a c	laim for foreign priority under	35 U.S.C.	§ 119(a)-(d).
a) ☐ All b) ☐ Some* c) ☐ None	e of:		
	ty documents have been received		1
			lication No
 Copies of the certified copie application from the *See the attached detailed Office act 	es of the priority documents had International Bureau (PCT Rule tion for a list of the certified co	17.2(a)).	
14) Acknowledgement is made of a c	laim for domestic priority unde	r 35 U.S.C	C. § 119(e).
Attachment(s)			
15) Notice of References Cited (PTO-892)	18) 🔲 Interview	Summary (PTC	0-413) Paper No(s)
16) Notice of Draftsperson's Patent Drawing Review (P			t Application (PTO-152)
17) Information Disclosure Statement(s) (PTO-1449) Pa	per No(s) 20) Other:		

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The amendment filed 2/26/02 is acknowledged. Claims 27-29, 31, 33 and 41-67 are being considered on the merits.

Claims 1-26 and 34-36 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-53 and 60-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41-53 fail to find proper antecedent basis in claims 28 and/or 29 for "the granulate". These claims are drawn to a composition comprising granular particles.

Claims 46, 47, 60 and 61 are vague and indefinite as well as incorrect in the use of the symbol " Ω " rather than " ω ". Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27, 28, 29, 41, 46, 54 are/remain

rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Parker *et al.* for the reasons as stated in the last Office action and the further reasons below.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that the process taught by Parker is not extrusion. However, the claims under examination are not directed to a process, but rather to a granular product. Counsel argues that extrudates have different physical characteristics as compared to the non-extruded products. In addition counsel contends that extruded products have porous structures while aggregates do not. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence. The extrusion product described at page 19, line 23 of the instant specification is not the subject of the claims under examination. There is no clear indication of the percentage of granular particles comprised by the composition of claims 28, 29, and 54, for example.

In addition, applicant has failed to substantiate the bald statement that one of ordinary skill would conclude that because Parker does not mention the presence of pores in the microbial granulates disclosed, such pores are necessarily absent. It is also noted that the extent of porosity of the instant granules is not claim designated. In addition claim 28, for example is directed to "pores and/or channels", while claim 29 does not require porosity. It is submitted that the composition of Parker at least possesses "channels" to some extent. Thus, whether the yeasts of Parker can or cannot be dispersed in water is immaterial to the invention as claimed. An extractant solvent such as water or an organic solvent would reasonably be expected to extract desired compounds from the compositions of the instant invention or the composition of Parker through pores and/or channels. The reference composition and claimed compositions are similarly directed to dehydrated microbial biomass in granular or particulate form.

Arguments directed to the use of the microorganisms in Parker and the asserted utility of the invention are not material to distinguishing the reference material over the claimed invention.

With regard to arguments pertaining to random sizing and shapes, it is noted that only claim 33 has limitations regarding the size of the granular particles or dried granules. Claim 33 is not included in this rejection.

Furthermore, the composition is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

The claims are not directed to a yeast, fungus or bacterium that is monosized, porous and not instantly wettable (Response, page 12, paragraph 4).

Applicant has failed to demonstrate differences in the dehydrated microbial biomass in granular or particulate form claimed over the reference with appropriate objective evidence.

Therefore the rejection is deemed proper and it is adhered to.

Claims 27-29, 31, 33 and 41-67 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Carduck *et al.* taken with Parker *et al.* and Dsiezak and further taken with Akimoto *et al.* and Casey *et al.* for the reasons as stated in the last Office action and the further reasons below.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the references.

Applicants argue that the live yeasts of Carduck *et al.* are intended to be used for bakery applications, while acknowledging that the product is produced by extrusion. Applicants also argue that the killed cell products of Dsiezak and Parker would not be useful to a baker. However, the use of killed biomass is well recognized in the art as a suitable additive for food and feeds.

Akimoto and Casey were cited to address the claim limitations directed to the content of specific desired compounds, such as unsaturated fatty acids. While these references admittedly are not directed to the production of extruded cell biomass, they are cited as evidence that processes of extraction of biomass for desired compounds is old and well known in the art.

Contrary to applicant's argument, it is well established that motivation for combining references need not come from the references themselves, as long as applicant's disclosure is not improperly used in a hindsight reconstruction of the claimed invention. See Ex parte Levengood, 28 USPQ2d 1300 (1993), at 1301. ("Motivation for combining the references need not be explicitly found in the references themselves. Indeed, the examiner may provide an explanation based on logic and sound scientific reasoning that will support a holding of obviousness.")(Citations omitted.)

Therefore, applicant's contention that there is "nothing in Carduck, Dsiezak or Parker about obtaining a more digestible bakery or alcoholic product" is misplaced. The supplementation of foods with brewer's yeast for example is well known, particularly as a rich sources of B vitamins. Whether or not a proprietary product such as Marmite would be added to bread or beer, is not relevant to the obviousness rejection made.

In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgement on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. *In re McLaughlin*, 443 F.2d 1392; 170 USPO 209 (CCPA 1971).

Specifically, applicants argue that none of the references suggest that extrudates such as those of Carduck may be used in solvent extraction. However, with all due respect it is noted that the claims are not directed to the use of extrudates in solvent extraction, but merely to an extrudate such as that of Carduck wherein the cells are dead rather than alive. The motivation to

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provide substantially similar preparations of dried, granular, porous compositions containing dead cells is adequately provided by Parker and Dsiezak.

Accordingly, applicant has not rebutted the strong *prima facie* case of obviousness made out over the references. Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592, (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx

Primary Examiner

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